

REMARKS

This paper responds to the FINAL Office Action sent on November 18, 2011.

Status of the Application

The disclosure is amended at page 1 to update the status of the parent application and to correct a typographical error.

Claims 1-3, 6, 8, 10, 25, 37-40, 78-81, and 83 are amended, no claims are cancelled, and claims 84-101 are added. Claims 4, 5, 7, 9, 11, 13, 16, 21, 22, 24, 27-30, 34, 36, 41-43, and 46-73 were previously cancelled. As a result, claims 1-3, 6, 8, 10, 12, 14, 15, 17-20, 23, 25, 26, 31-33, 35, 37-40, 44, 45, and 74-101 are pending in this application.

Claims 1 and 37 have been amended to recite that the film-former is a non-foaming film-former that forms a stable, breathable film that is not a foam. Support for this amendment is found at least at page 10, paragraph [0040] of the specification, wherein “the valve actuator [of the dispenser] can be any actuator which produces a spray and not a foam at the nozzle.”

Claims 1-3, 6, 8, 10, 25, 37-40, and 78-81 are amended to recite that the percentages are in weight percent. Support for this amendment is found at least in Examples 1-12 wherein the amounts of the ingredients are given in weight percent (Percent w/w).

Claims 37, 80, and 81 have been amended to recite that the vehicle is a non-aqueous vehicle. Support for this amendment is found at page 8, paragraph [0033] of the specification.

Claim 83 is amended to recite that the water soluble additive may include Tweens, vitamin E (TGPS) and glycerol. Support for the term “Tweens” is found at least at page 8, paragraph [0032], and in claims 20, 33. Support for the term “vitamin E (TGPS)” is found at least at page 4, paragraph [0020], at page at 7, paragraph [0030], in Examples 1-12, and in claim 33. Support for the term “glycerol” is found at least at page 8, paragraph [0034], and in originally filed claim 29.

New claims 84-101 have been added to recite specific embodiments of non-foaming sprayable compositions and non-foaming compositions; wherein the medicament is testosterone

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(claims 84-92) or estradiol (claims 93-101), the film-former is copovidone, and the vehicle is ethanol. Support for the medicament as testosterone or estradiol is found in the specification at least at page 6, paragraph [0027]; support for the film-former as copovidone (i.e. copovidone is povidone vinyl acetate copolymer) is found at page 7, paragraph [0028]; and support for the vehicle as ethanol is found at page 8, paragraph [0033] (i.e. absolute alcohol). Support for various amounts of materials is found in the specification at page 4, paragraph [0021]. Support for other embodiments of new claims 84-101 is found at least in currently pending and previously filed claims.

No new matter has been added with these amendments.

Request for Telephonic Interview

Applicant's counsel, Louis M. Leichter, hereby respectfully and formally requests a telephonic interview under MPEP § 713 with the Examiner, before issuance of any further Official Action in the present matter, to discuss the present amendments and remarks and all rejections. It is believed that such a telephonic interview will help facilitate and expedite the examination of this case. The Examiner is invited to call Applicant's counsel at (612) 373-6961 to schedule an interview at a mutually convenient time.

Rejections Under 35 U.S.C. § 103

Claims 1-3, 6, 8, 10, 12, 14, 15, 17-20, 23, 25, 26, 31-33, 35, 37-40, 44, 45, and 74-83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of Osipow et al. (U.S. Patent 4,328,319; hereafter '319) in view of Biedermann et al. (U.S. Patent 5,980,921; hereafter '921).

The Office Action asserts that the foamed products of Osipow ('319) meet the limitations of Applicants' stable, breathable film formed upon application to a surface except for the presence of a plasticizer. Biedermann ('921) is provided to disclose several plasticizers for use in topical compositions. In so far as this rejection pertains to the claims as amended, Applicants respectfully traverse this rejection.

Claim 1 has been amended to recite that the film-former is a non-foaming film former that forms a stable, non-foam, breathable film upon application to a surface. Support for this amendment is found at least at page 10, paragraph [0040] of the specification, wherein “the valve actuator [of the dispenser] can be any actuator which produces a spray and not a foam at the nozzle.” Claim 1 now recites various film-forming polymers that can be used to prepare Applicants’ non-foamed films. In short, Applicants’ films are not foamed.

In contrast, Osipow discloses “compositions including a film-forming synthetic polymer that are capable of forming foamed structures containing open and closed cells...” (Osipow ‘319, Abstract). In short, Osipow only teaches foam-forming compositions. Applicants assert that, given the disclosure of the foamed compositions contained in Osipow, one skilled in the art would not be led to prepare non-foamed compositions. To do so would require removing an essential feature of Osipow, and Osipow provides no teaching, suggestion, or motivation to do so. Thus, Osipow teaches away from Applicants’ non-foamed film-forming compositions.

The addition of Biedermann (‘921) fails to cure the deficiencies of Osipow. Biedermann is provided merely to disclose the use of plasticizers in topical compositions. However, Biedermann provides no reason to modify the foam-forming compositions of Osipow to prepare Applicants’ claimed non-foam, film-forming compositions.

In addition, Biedermann does not use a non-aqueous vehicle for his composition. Biedermann prepares his compositions as an oil-in-water emulsion (Biedermann ‘921; column 8, lines 56-67). In contrast, Applicants’ compositions as now claimed do not contain water and are not coated from water. Applicants’ compositions are contained in a non-aqueous vehicle (Specification; page 8, paragraph [0033]; Examples 1-12). This is to enable a porous, breathable film to be formed rapidly upon evaporation of the solvent and exposure to moisture. (Specification; page 7, paragraph [0029]). The “water soluble” polymers and other water soluble additives in Applicants’ sprayable composition are water soluble so that they “can partially dissolve on exposure to moisture (from the skin or air), the dissolution resulting in the formation of a porous film (Specification, page 7, paragraph [0029]) as well as to be readily washed off with water” (Specification, page 9, paragraph [0038]).

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In view of the above amendments and remarks, Applicants respectfully request withdrawal of this rejection and early allowance of claims 1-3, 6, 8, 10, 12, 14, 15, 17-20, 23, 25, 26, 31-33, 35, 37-40, 44, 45, and 74-83.

New Claims

New claims 84-101 have been added to recite specific embodiments of non-foaming sprayable compositions and non-foaming compositions; wherein the medicament is testosterone, the film-former is copovidone, and the vehicle is ethanol. Support for the medicament as testosterone or estradiol is found at page 6, paragraph [0027]; support for the film-former as copovidone (i.e. povidone vinyl acetate copolymer) is found at page 7, paragraph [0028]; and support for the vehicle as ethanol is found at page 8, paragraph [0033] (i.e. absolute alcohol). Support for various other embodiments of new claims 84-101 is found in currently pending and previously filed claims.

Additional Remarks

Applicants would also like to point out several other distinctions between their invention as claimed, and the Osipow ('319) patent.

Osipow ('319) discloses that, if the coating material is a surfactant, it assists in the dissolution of the polymer by aiding in dispersing the coated polymer particles in the propellant. See, Column 4 lines 33-35. Osipow goes on to say that surfactants are an especially preferred class of coating materials. See, column 5, lines 4-5. In contrast, Applicants' presently claimed compositions do not involve any coating of the polymer with surfactant.

Osipow states "a solution or dispersion of the coating material in a liquid solvent or suspending agent in which the coating material is insoluble is prepared, but the liquid solvent or suspending agent should not be a solvent for the polymer. See, column 5, lines 45-48. In contrast, Applicants' polymer, suspending agents and other ingredients, as presently claimed, are dissolved or dispersed in a single solvent (e.g., ethanol)

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Further, Osipow states that “any additive that is present is dissolved in the propellant with the polymer, and is deposited in the cells (i.e. the cells of the foam) of the structure when the propellant is volatilized as the structure is being formed. Any non-propellant liquid will also be deposited in the cells, if it is insoluble in the polymer. Any additive dissolved in this liquid will be applied with the liquid from the cells of the structure when the foamed structure is used. See, column 7, lines 40-47. In contrast, the ingredients in Applicants’ presently claimed formulation are dissolved or dispersed in a single solvent only and no such entrapment of the additives occurs. In addition, because Applicants’ presently claimed composition does not form a foam, entrapment of ingredients in the cells of the foam does not occur.

Additionally, Osipow states “[t]he relative proportions of propellant and polymer in the propellant compositions of the invention determine to a considerable extent the nature of the foamed structure that is formed...” “If the proportion of polymer is too low (and usually the lower proportion is not less than approximately 10% polymer by weight of the composition) a cohesive foamed structure is not formed, but instead a bubbly, sticky, flowable mass is obtained.” See, column 9, lines 38-41 and 43-47. In contrast, Applicants’ presently claimed compositions contain a non-foaming, film-forming polymer comprising from about 0.0001% to about 10% w/w of the composition. Thus, Applicants’ presently claimed compositions use a much lower amount of polymer.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6961 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,
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Date February 16, 2011

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